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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,318	03/31/2004	Ron Wortley	11984.6	5172
27966	7590	08/10/2007		
KENNETH E. HORTON KIRTON & MCCONKLE 60 EAST SOUTH TEMPLE SUITE 1800 SALT LAKE CITY, UT 84111			EXAMINER BACHMAN, LINDSEY MICHELE	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 08/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/814,318

Applicant(s)

WORTLEY ET AL.

Examiner

Lindsey Bachman

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-21 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 October 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed on 20 April 2007.

Claim Objections

Claims 2, 3, 6, 7, 14 and 27 are objected to because of the following informalities: it is unclear as to whether the catheter is being claimed as part of the invention. Applicant refers to the catheter functionally in claims 2, 3, 6, 7, 14 and 27, yet Applicant's arguments consider the catheter structurally. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al (US Patent Application 2002/0099327).

Claim 1 and 5: Wilson'327 discloses a multi-lumen catheter capable of being used as a tunneler comprising a tip (20) with gripping means (38, 40) and a plurality of flexible shaft members (14, 16) having dissimilar lengths (Figure 1) extending from tip (20).

Claims 2, 3, 6, and 7: Wilson'327 discloses a means for retaining the shaft members (14, 16) in the lumen of a catheter (12) comprising a protrusion (26a, 28a).

Claims 4 and 8: Wilson'327 shows that the difference in the lengths of the shaft members (14, 16) is up to 20 percent (Figure 1).

Claim 9: Wilson'327 discloses a shaft (12) that is removably connected to tip (20).

Claim 10: Wilson'327 discloses a sheath (34) that covers the portion of the shaft (12) and the tip (20) that are connected.

Claims 11 and 12: Sheath (34) contains a retaining ring to retain the sheath (34) on tip (20) (paragraph [0029]) and the sheath (34) contains a retaining ring for retaining the sheath (34) on the shaft (12) (paragraph [0024]). Protrusions (26a, 28a) exist on shaft (21).

Claim 13: The retaining ring inside sheath (34) compliments protrusions (26a, 28a) on shaft (12) (paragraph [0029]).

Claim 14: The retaining ring inside sheath (34) compliments protrusions (26a, 28a) on shaft (12) (paragraph [0029]).

Claim 15: Wilson'327 discloses a multi-lumen catheter capable of being used as a tunneler comprising a tip (20) with gripping means (38, 40) and a plurality of flexible shaft members (14, 16) having dissimilar lengths (Figure 1) extending from tip (20). Shaft (12) is removably connected to tip (20) and sheath (34) covers the portion of the tip (20) and shaft (12) that are connected.

Claim 16: Wilson'327 discloses that a means for retaining the shaft members (14, 16) in the lumen of a catheter (12) comprising a protrusion (21a) located on the outside of shaft members (14, 16).

Claims 17 and 18: Sheath (34) contains a retaining ring to retain the sheath (34) on tip (20) (paragraph [0029]) and the sheath (34) contains a retaining ring for retaining the sheath (34) on the shaft (12) (paragraph [0024]). Protrusions (21a) exist on shaft (21).

Claim 19: The retaining ring inside sheath (34) compliments protrusions (21a) on shaft (12) (paragraph [0029]).

Claim 20: The retaining ring inside sheath (34) compliments protrusions (21a) on shaft (12) (paragraph [0029]).

Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Zawacki et al. (US Patent Application 2004/0167463).

Zawacki'463 discloses a multi-lumen catheter (410) and a tunneler with a tip (430) containing gripping means (anything can be gripped) and a plurality of shaft members (440, 450) extending therefrom having dissimilar lengths (see Figure 16, or 17).

Claim 26 is rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et al. (US Patent 6,921,396).

Claims 26: Wilson'396 discloses a device that contains a tip (14) containing gripping means (anything can be gripped); a rigid tunneler shaft (12) and a plurality of flexible tip members (19, 23) having dissimilar lengths (see Figure 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imran (US Patent 5,964,796) and Vardi, et al. (WO 02/076333).

Imran'796 teaches the use of a multi-lumen catheter (11) with a multi-lumen tunneler (12). The tunneler (12) contains a tip (12) with a gripping means (21) and a plurality of flexible shaft members (26). Imran'796 does not teach a multi-lumen tunneler in which the shafts have different lengths.

Vardi'333 teaches an introducer in which the shaft members have different lengths (Figure 5 and page 8, lines 3-8) so that the introducer can be used for accessing a bifurcated vessel (page 6, lines 1-12). It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by

Imran'796 with introducer shaft members having different lengths in order to create simultaneous access to the two vessels in a bifurcated vessel.

Claims 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson'396, as applied to Claim 26, in further view of Zawacki et al. (US Patent Application 2004/067463).

Claim 28 rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson'396 in view of Zawacki'463.

Wilson'396 teaches the limitations of Claim 27 and 28, including a device that contains a tip (14) containing gripping means (anything can be gripped); a rigid tunneler shaft (12) and a plurality of flexible tip members (19, 23) having dissimilar lengths (see Figure 1). Wilson'396 does not teach a protrusion on the tip shaft members.

Zawacki'463 teaches a device that contains a plurality of flexible tip members (440, 450 shown in Figure 16) having different lengths that contains a protrusion (480) in order to move edges of the tips away from the inside surface of a delivery sheath. It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by Wilson'396, with protrusions as taught by Zawacki'463, because it helps move the sharp tips away from the inside of the sheath (Wilson'396 also has sharp tips, as shown in Figure 1, especially seen at 21 and sheaths (elements 200, 300)).

Response to Arguments

Applicant's arguments filed 20 April 2007 have been fully considered but they are not persuasive.

Claims 1-20: Applicant's arguments filed 13 October 2006 have been fully considered but they are not persuasive. In response to applicant's argument that the device taught by Wilson'327 is catheter not a tunneler and therefore does not meet the requirements of 35 USC 102(b), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As shown in the above rejection, Wilson'327 meets all the structural limitations of Applicant's claims.

Applicant has not presented new arguments with respect to Claim 21.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **WO MONTHS** of the mailing date of this final action and the advisory action is not

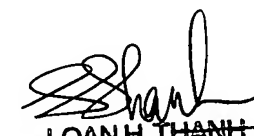
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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PRIMARY EXAMINER